

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
23 September 2004 (23.09.2004)

PCT

(10) International Publication Number
WO 2004/080514 A1

(51) International Patent Classification⁷: **A61M 5/50**

(21) International Application Number:
PCT/IB2004/000699

(22) International Filing Date: 12 March 2004 (12.03.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
200300652 14 March 2003 (14.03.2003) ES

(71) Applicant: **TYCO ELECTRONICS AMP ESPAÑA**,
S.A. [ES/ES]; Muntaner 249, 5a, E-08021 Barcelona (ES).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CIRAC SOLE**,
Xavier [ES/ES]; Batlles, 4, E-08330 Premià de Mar
(Barcelona) (ES). **BATLLO ROSES**, Luís [ES/ES];
Ravella, 12 àtico, E-08021 Barcelona (ES). **HERRANZ**,
Ana, Maria [ES/ES]; C/Barcelona 146, 2º 2a, E-08780
Pallejá (Barcelona) (ES).

(74) Agents: **HEINZ-SCHAEFER**, Marion et al.; Tyco Elec-
tronics Logistics AG, Ampèrestrasse 3, CH-9323 Steinach
(SG) (CH).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

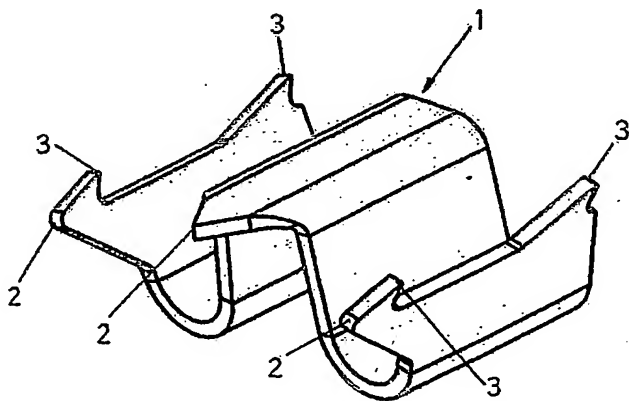
(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Euro-
pean (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,
GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: SAFETY INSERT FOR SINGLE-USE DISPOSABLE SYRINGES



(57) Abstract: Safety insert for disposable syringes,
comprising at least one attachment means whose point
allows advance of the stem during injection of the
syringe content and prevents its retraction once said
injection is performed on attaching to the inner walls
of the cylinder, and having at least one piercing means
with a point at its end able to dig into the plunger and
pass through its wall, thus breaking the tightness of the
compartment of the cylinder intended to contain the
substance to be injected when retraction of the stem is
attempted following the injection.

WO 2004/080514 A1

4/10/05
1**Safety insert for single-use disposable syringes**

The present invention relates to a safety insert for single-use disposable syringes which can be introduced into the interior thereof.

The use of disposable syringes is currently of great importance for avoiding contagion of infectious diseases, such as hepatitis or AIDS, both for health personnel and actual users of said syringes.

These syringes are very simple in construction since they usually consist of a cylindrical element, generally made of plastics material, which ends at one end in a nozzle and at the other end in a circular opening, and of an internal element which at one end has a plunger which produces a seal and at the other end a base for pushing or pulling same, and a stem which joins the two aforementioned end elements.

In spite of the fact that these disposable syringes, generally made of plastics material, are sold at very low cost and are provided for single use, re-use thereof is frequent, particularly by drug addicts who inject substances intravenously, which involves an obvious and certain risk of infection.

European patent application EP 494 289 A1 describes a single-use syringe in which, by means of radial arms that are sharpened at their ends and articulated to the end of the plunger, it is possible to cut the wall of the syringe cylinder, thus breaking its seal. However, this device has the drawback that the sharp edges project externally and, while

preventing reuse of the syringe, can cause infections owing to potential cuts from said sharp edges.

There are numerous single-use syringes on the market which, after use, impede withdrawal of the interior plunger by mechanical means, many of them fixed to the syringe itself, and thus make their manufacture more expensive.

European patent EP 0 489 750 describes an insert for preventing reuse of plastic syringes.. Said element can be inserted through the open end of the syringe between the internal wall of the cylindrical part of the syringe and the stem of the interior plunger. It has several tabs with points or ends which are fixed to the stem and move jointly therewith only when said stem is displaced toward the nozzle, and other tabs with points or ends, of which the inclination is such that they are fixed to the cylindrical wall when the stem is displaced away from the nozzle. A final blocked position of the nozzle is thus achieved after the syringe has been used, thus avoiding a withdrawal movement of said nozzle once the syringe has been emptied, although said construction may be sensitive to slight clearance.

The object of the present invention is to provide a safety insert for disposable syringes which avoids the drawbacks of the prior art and which more reliably prevents re-use of said syringe.

It has been found that this can be achieved with means which, in the event of an attempt to withdraw the plunger after use of the syringe, break the seal of the cylindrical compartment intended to contain the substance for injection.

The invention relates to a safety insert for disposable syringes which comprises at least one perforating means with a point at its end that is capable of penetrating the plunger and passing through its wall, thus breaking the seal of the cylindrical compartment intended to contain the substance for injection when an attempt is made to withdraw the plunger after injection.

Other characteristics and advantages of the present invention will emerge from the detailed description hereinafter which makes reference to the accompanying drawings, in which:

Fig. 1 shows a perspective view of the subject of the present invention,

Fig. 2 shows a perspective view of a syringe in the initial position prior to its use,

Fig. 3 shows a perspective view of the subject of the present invention located on the interior stem and in its initial position prior to use of the syringe, without showing the cylindrical wall element,

Fig. 4 shows a perspective view of a syringe after suction or filling have taken place,

Fig. 5 shows a perspective view of the subject of the present invention located on the interior stem in its position after suction or filling have taken place, without showing the cylindrical wall element,

Fig. 6 shows a perspective view of a syringe in the final empty position,

Fig. 7 shows a perspective view of the subject of the present invention located on the interior stem in its final empty position, without showing the cylindrical wall element,

Fig. 8 shows a perspective view of an insert according to the present invention,

Fig. 9 shows a perspective view of a syringe in the initial position prior to its use,

Fig. 10 shows a perspective view of the subject of Fig. 8 located on the interior stem and in its initial position prior to use of the syringe, without showing the cylindrical wall element,

Fig. 11 shows a perspective view of a syringe after suction or filling have taken place,

Fig. 12 shows a perspective view of the subject of Fig. 8 located on the interior stem in its position after suction or filling have taken place, without showing the cylindrical wall element,

Fig. 13 shows a perspective view of a syringe in the final empty position, and

Fig. 14 shows a perspective view of the subject of Fig. 8 located on the interior stem in the final, empty position, without showing the cylindrical wall element.

As can be seen in Fig. 1, the insert 1 shown in this figure has an approximately W-shaped profile and has two pairs of fixing means 3 and perforating means 2, of which two are lateral and one is central, each of them having the shape of a gaff, with their respective points. The profile of the insert 1 can have two symmetrical lateral portions and one central portion capable of settling on one of the longitudinal walls of the stem of the syringe. In said figure it can be seen that the lateral perforating gaffs are adjacent to the respective front fixing gaffs.

Fig. 2 shows a syringe 4 in its initial position prior to its use. Said syringe 4 has a cylindrical wall element 5 which ends at one end in a nozzle 6 and at the other end in a circular opening surrounded by a lower ring 7. The internal element 8 has, at one end, a plunger 10 and at the other end a pushing base 11, both joined by an intermediate stem 9 formed by perpendicular walls 12 with an X-shaped portion. Said stem 9 also contains at least one interior ring 13.

Fig. 3 shows the initial position of the element 1 of Fig. 1 on said stem 9 and without showing the cylindrical wall element 5.

Fig. 4 shows the syringe 4 once suction has been produced, with total withdrawal of the stem 9. On the other hand, Fig. 5 shows the position of the element 1 of Fig. 1 on the interior stem 9 of the syringe 4 once suction has been produced, without showing the cylindrical wall element 5.

Fig. 6 shows the syringe 4 once it has been emptied, with total advancement of the stem 9, and Fig. 7 shows the position of the element 1 of Fig. 1 on the interior stem 9 of the syringe 4 once it has been emptied, without showing the cylindrical wall element 5.

Fig. 8 shows an insert 14 with an approximately V-shaped profile which has a pair of protection plates 15 in its lower part, to prevent manipulations. Each of the two portions of said V is capable of being supported on the respective longitudinal wall 12 of the stem 9 of the syringe 4. In this figure this element also has its perforating gaffs adjacent to the front fixing gaffs.

Fig. 9 to 14 show the positions of the syringe 4 and the insert 14 of Fig. 8 during its use.

Fig. 9 shows a syringe 4 in its initial position prior to its use and Fig. 10 shows the initial position of the element 14 of Fig. 8 on said stem 9 and without showing the cylindrical wall element 5.

Fig. 11 shows the syringe 4 once air intake has been produced, with total withdrawal of the stem 9. On the other hand, Fig. 12 shows the position of the element 14 in Fig. 8 on the interior stem 9 of the syringe once air intake has been produced, without showing the cylindrical wall element 5.

Fig. 13 shows the syringe 4 once it has been emptied, with total advancement of the stem 9, and Fig. 14 shows the position of the element 14 of Fig. 8 on the interior stem 9 of

the syringe 4 once said evacuation has been produced, without showing the cylindrical wall element 5.

The shape of the retention gaffs with their respective points means that during evacuation (advancement of the stem 9), the insert 1, 14 can advance with the stem 9 but cannot move backwards, owing to the fact that its retention gaffs 3 impede said withdrawal by penetrating in the internal wall of the cylindrical element 5 of the syringe 4.

Therefore, on arriving at the final evacuation position the stem 9 with the insert 1, 14 cannot move backwards and said insert 1, 14 will remain in its end position. If there is any attempt to pull the stem 9 back with the intention of re-using the syringe 4, the perforating gaff 2 will penetrate on the plunger 10, passing through its wall and thus breaking the seal of the syringe 4.

It is obvious that modifications can be made to the invention within the scope thereof, without the invention having to be considered limited to the embodiment described but only to the content of the following claims.

Claims

1. Safety insert for single-use disposable syringes comprising at least one fixing means (3), that allows advancement of the stem (9) during injection of the contents of the syringe (4) and impedes its withdrawal once the injection has been given, by fixing itself to the interior walls of the cylinder (5), characterised in that it has at least one perforating means (2) with a point at its end that is capable of penetrating the plunger (10) and passing through its wall, thus breaking the seal of the cylindrical compartment (5) intended to contain the substance for injection when there is an attempt to withdraw the stem (9) after injection.

2. Safety insert for single-use disposable syringes according to claim 1, characterised in that its profile is approximately "W" shaped.

3. Safety insert for single-use disposable syringes according to claim 2, characterised in that its profile has two symmetrical lateral portions and one central portion capable of settling on one of the longitudinal walls of the stem (9) of the syringe (4).

4. Safety insert for single-use disposable syringes according to any of the preceding claims, characterised in that it has at least one pair of gaffs as fixing means (3).

5. Safety insert for single-use disposable syringes according to any of the preceding claims, characterised in that it has two pairs of gaffs as fixing means (3).

6. Safety insert for single-use disposable syringes according to any of the preceding claims, characterised in that it has two lateral gaffs and one central gaff as perforating means (2).

7. Safety insert for single-use disposable syringes according to claim 1, characterised in that its profile is approximately "V" shaped with two portions.

8. Safety insert for single-use disposable syringes according to claim 7, characterised in that each of its two portions is capable of being supported on the respective longitudinal wall (12) of the stem (9) of the syringe (4).

9. Safety insert for single-use disposable syringes according to claims 7 and 8, characterised in that it has at least one pair of gaffs as fixing means (3).

10. Safety insert for single-use disposable syringes according to claims 7, 8 and 9, characterised in that it has two pairs of gaffs as fixing means (3).

11. Safety insert for single-use disposable syringes according to claims 7, 8, 9 and 10, characterised in that it has two lateral gaffs as perforating means (2).

12. Safety insert for single-use disposable syringes according to claims 8, 9, 10 and 11, characterised in that it has at least one end plate (15) to prevent manipulations.

13. Safety insert for single-use disposable syringes according to any of the preceding claims, characterised in that at least one perforating means (2) is adjacent to the respective front fixing means (3).

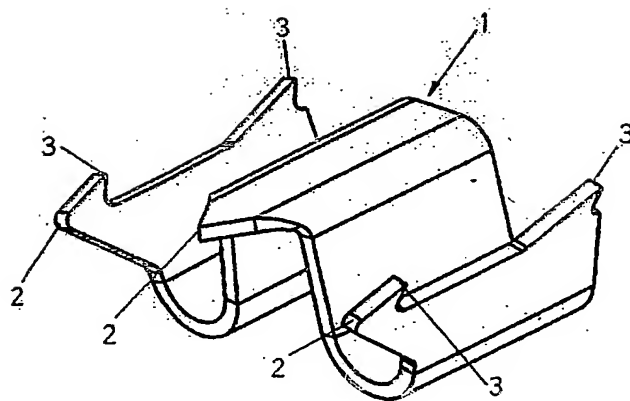


FIG. 1

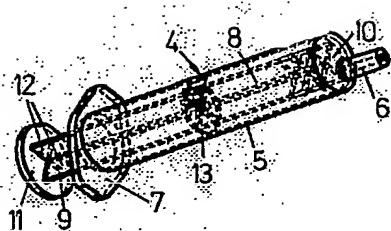


FIG. 2

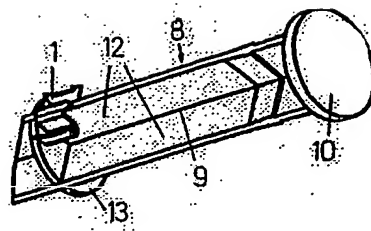


FIG. 3

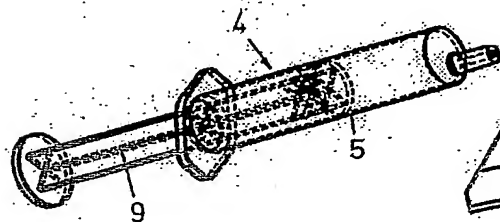


FIG. 4

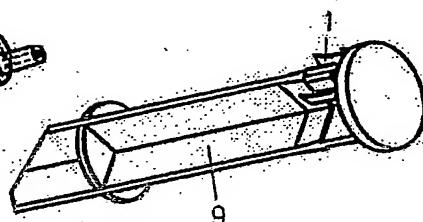


FIG. 5

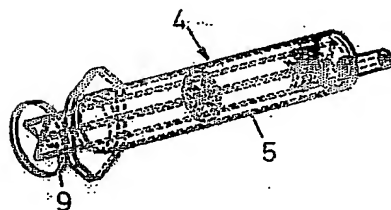


FIG. 6

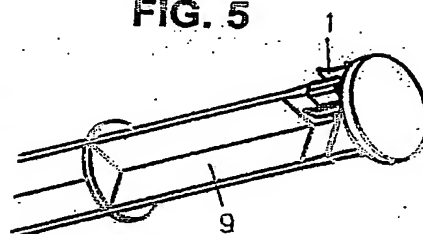


FIG. 7

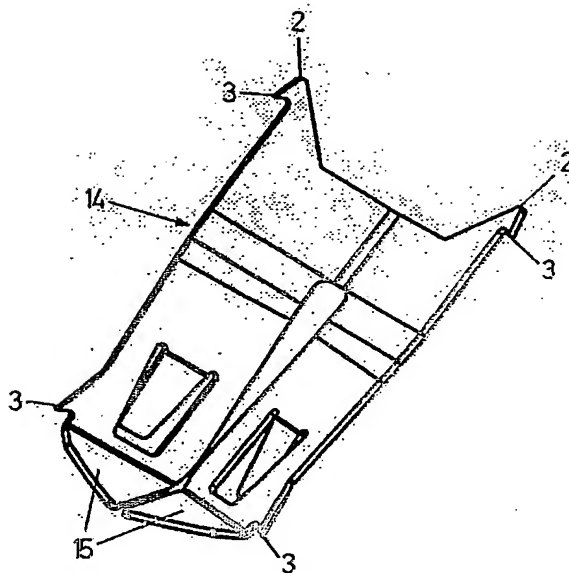


FIG. 8

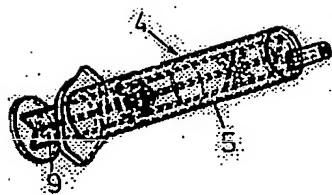


FIG. 9

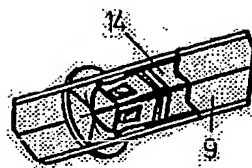


FIG. 10

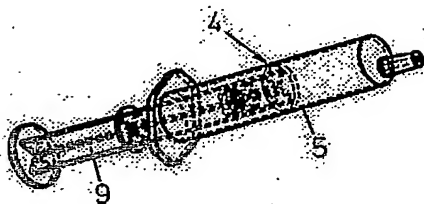


FIG. 11

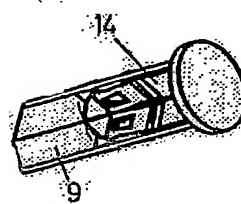


FIG. 12

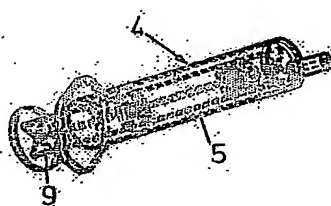


FIG. 13

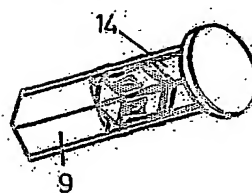


FIG. 14

INTERNATIONAL SEARCH REPORT

Int. nat. Application No.
PCT/IB2004/000699

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99/44661 A (ANTOLINI JUNIOR ANTONIO CARLOS ; PAIVA MARQUES JOSE LUIZ DE (BR)) 10 September 1999 (1999-09-10) abstract; claim 5	1
A	US 5 019 046 A (KOHLE REINHARD) 28 May 1991 (1991-05-28) abstract	1
A	GB 2 187 961 A (MORLEY ROGER HUBERT; POWER RICHARD KITLEY) 23 September 1987 (1987-09-23) abstract	1
A	WO 83/00438 A (MERCANTILE & TECHNICAL PROMOTI) 17 February 1983 (1983-02-17) abstract	1
-/-		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

29 June 2004

Date of mailing of the international search report

06/07/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Nielsen, M

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/IB2004/000699

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 205 825 A (ALLISON ALAN C ET AL) 27 April 1993 (1993-04-27) abstract	1
A	US 5 021 047 A (MOVERN JOHN B) 4 June 1991 (1991-06-04) abstract	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No
PCT/IB2004/000699

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9944661	A	10-09-1999	AU 6388498 A WO 9944661 A1	20-09-1999 10-09-1999
US 5019046	A	28-05-1991	DE 3901484 A1 AT 92348 T DE 59002125 D1 EP 0379223 A2	07-12-1989 15-08-1993 09-09-1993 25-07-1990
GB 2187961	A	23-09-1987	NONE	
WO 8300438	A	17-02-1983	WO 8300438 A1 AU 7531081 A EP 0085043 A1 JP 58501497 A NO 831123 A	17-02-1983 22-02-1983 10-08-1983 08-09-1983 28-03-1983
US 5205825	A	27-04-1993	AT 136798 T CA 2060177 A1 DE 69026618 D1 DE 69026618 T2 DK 489750 T3 EP 0489750 A1 ES 2089021 T3 WO 9101768 A1	15-05-1996 08-02-1991 23-05-1996 20-02-1997 26-08-1996 17-06-1992 01-10-1996 21-02-1991
US 5021047	A	04-06-1991	US 5183466 A	02-02-1993